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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,424	07/29/2003	Frieder Braunschweig	P0010978.00	6026

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MEDTRONIC, INC.
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EXAMINER

PATEL, NATASHA

ART UNIT	PAPER NUMBER
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3766

MAIL DATE	DELIVERY MODE
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08/22/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No. 10/629,424	Applicant(s) BRAUNSCHWEIG ET AL.	
	Examiner Natasha N. Patel	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-12 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-12 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 5/18/07 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/16/03 and 3/17/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed on May 18, 2007 has been received and considered. By this amendment, Claims 6 and 13 have been cancelled, Claims 1, 2, 4, 5, 7, 8, 12, and 14 have been amended, and no claims have been added. Thus, Claims 1-5, 7-12, and 14 are now pending in this application.

Drawings

1. In view of the Applicant's inclusion of Figures 1-6, the Examiner is withdrawing the objection that was made against the drawings in the previous Office Action.
2. However, Figures 1-6 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Response to Arguments

3. Applicant's arguments filed 5/18/2007 have been fully considered but they are not persuasive. Applicant claims that Kieval does not provide for delivery of a cardiac pacing therapy based on a lowest measured estimated pulmonary artery diastolic pressure (ePAD) value. However, Kieval does in fact disclose determining the lowest value of ePAD for optimizing the AV delay (see col. 8, lines 37-40).

Claim Rejections - 35 USC § 112

4. Claims 5 and 7-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There does not seem to be any mention of chronic delivery of cardiac pacing in the Specification.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-5, 7-8, 11-12 and 14 are rejected under 35 U.S.C. 103(a) as being obvious over Kieval et al. (US Patent 5,626,623) in view of Bornzin (US Patent 5,891,176).

7. Regarding Claim 1, Kieval discloses a system for collecting hemodynamic data from a patient (see col. 3, lines 42-44) and utilizing said data to optimize a cardiac pacing regimen for said patient (see col. 4, lines 10-13), comprising: a means for collecting hemodynamic data of a patient (see absolute pressure sensor 160 and microcomputer 302; col. 3, lines 42-44) and for storing said collected hemodynamic

Art Unit: 3766

data (see RAM/ROM 310, 312, 314), wherein said hemodynamic data consists of a lowest estimated pulmonary artery diastolic pressure (ePAD) value (see col. 11, lines 9-18); a means for monitoring and/or stimulating cardiac tissue (see IPG 100) of a patient to provide a desired cardiac rhythm and restore the desired cardiac rhythm (see col. 4, lines 40-43), and a means for utilizing the collected lowest ePAD value with the means for monitoring and/or stimulating cardiac tissue to optimize an atrio-ventricular (AV) interval for said patient (see col. 12, lines 12-17 and col. 17, lines 34-54). The examiner considers that although the hemodynamic data is stored in memory after it has already been processed, the data is still being stored in some way, shape, or form. Furthermore, the examiner considers that the hemodynamic data (RVP signal) is integrated into the pulse generator's pacing program to establish an optimal AV delay (see col. 17, lines 25-29), which consequently optimizes a hemodynamic characteristic of the patient. Although Kieval mentions activity levels (see col. 10, lines 41-42) and periods of rest (see col. 10, line 64), Kieval does not explicitly disclose that hemodynamic data is collected during both activity and rest. However, Bornzin discloses a similar optimization system, in which the monitoring means (physiologic sensor 12) collects (see col. 7, lines 5-10) during periods of rest and periods wherein said patient is performing the activities of daily living (see col. 8, lines 61-66). It would have been obvious to one of ordinary skill in the art at the time of the invention to collect hemodynamic data during periods of rest and during activity because Bornzin teaches the benefit of being able to differentiate between activity and rest in order to provide an appropriate therapy (see col. 2, lines 26-39).

8. Regarding Claim 2, Kieval discloses that the lowest ePAD value is collected using an absolute pressure sensor (see col. 8, lines 19-21) adapted to be fluidly coupled to a cardiac chamber of the patient (see Figure 4). The examiner considers that sensor 160 on lead 114 has the ability to be fluidly coupled. Furthermore, it has been held that the recitation that an element is "adapted to" perform function is not a positive limitation in any patentable sense (*In re Hutchinson*, 60 USPQ 138).

9. Regarding Claim 3, Kieval discloses that the means for monitoring and/or stimulating comprises a pulse generator (see col. 7, lines 54-55 and Figure 4).

10. Regarding Claims 5 and 14, Kieval discloses a method of optimizing hemodynamics of a patient (see col. 4, lines 10-13) having an implantable cardiac rhythm stimulation and monitoring device (see IPG circuit 300), comprising the steps of: collecting hemodynamic data from said patient (see col. 3, lines 42-44) with a hemodynamic monitor (see absolute pressure sensor 160 and microcomputer 302) adapted to be disposed in fluid contact with a volume of venous blood of said patient (see col. 5, lines 59-61), wherein the hemodynamic data consists of the lowest ePAD value (see col. 14, line 64-col. 15, line 10); storing said lowest ePAD value in a computer readable medium (see col. 13, lines 21-28). The examiner considers since the pressure sensor 160 is in the right ventricle and the venous blood enters the right ventricle, then the pressure sensor 160 is in fluid contact with the venous blood. Kieval discloses storing said collected hemodynamic data (see RAM/ROM 310, 312, 314). The examiner considers that although the hemodynamic data is stored in memory after it has already been processed, the data is still being stored in some way, shape, or form.

Art Unit: 3766

Kieval further discloses collecting cardiac event data from the patient (see col. 15, lines 40-46 and Figures 5 and 10) and storing the cardiac event data in a computer readable memory medium (see RAM/ROM 310, 312, 314). The examiner considers that although the ECG is stored in memory after it has already been processed, the ECG is still being stored in some way, shape, or form. Kieval discloses analyzing said lowest ePAD value in conjunction with said cardiac event data to determine an AV delay interval to optimize the hemodynamics of said patient, and providing said AV delay interval to an implantable cardiac rhythm stimulation and/or monitoring device (see Kieval, col. 17, lines 34-54) as an operating AV delay interval for chronic delivery of cardiac pacing therapy. The examiner considers that since the AV delay is continually updated, then the heart will be paced to reflect those changes chronically. Kieval does not disclose collecting hemodynamic data during activity levels above resting rate. Bornzin discloses performing this collection process during a period of time when a heart rate of the patient is elevated above a resting rate due to activity by said patient (see col. 9, lines 9-15 and col. 6, lines 6-14). The examiner considers the heart rate will inherently be higher during physical activity compared to the heart rate during rest. It would have been obvious to one of ordinary skill in the art at the time of the invention to collect hemodynamic data during periods activity because a patient will not always be at rest and Bornzin teaches the benefit of being able to provide an appropriate therapy at any activity level (see col. 5, lines 26-30).

11. Regarding Claim 7, Kieval discloses that the lowest ePAD value is collected at a pre-determined time of day and at a pre-determined interval (see col. 17, lines 34-38

and lines 66-67). The examiner considers since the initial step of the optimization method includes collecting hemodynamic data (see RVP signals, col. 3, lines 42-44) and the optimization method is performed at pre-determined times of the day, hemodynamic data is also collected at pre-determined times of the day.

12. Regarding Claim 8, Kieval discloses that during the providing step an A-V interval (see col. 17, lines 52-54) comprises a part of the cardiac stimulation sequence. The examiner considers that the main goal of the AV optimization method is to provide an optimized AV interval to the cardiac pacing regime so an AV interval must be provided to the cardiac stimulation sequence (see col. 4, lines 40-43).

13. Regarding Claims 11 and 12, Kieval discloses that the hemodynamic data is collected for a preselected period of time (see col. 4, lines 10-13), the preselected period of time being between a few minutes and several days (see col. 12, lines 46-49). The examiner considers that since the initial step of the optimization method includes collecting hemodynamic data (see RVP signals, col. 3, lines 42-44) and the optimization method is performed at pre-determined times of the day for a number of minutes, the collection of hemodynamic data also occurs at pre-determined times of the day for a few minutes.

14. Regarding Claim 14, see rejection of similarly worded Claim 5 above. As to a computer readable medium, Kieval discloses some type of instructions for performing this optimization method (see microcomputer 302 in Kieval, col. 9, line 64- col. 10, line 32).

15. Claims 4 and 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kieval et al. (US Patent 5,626,623) in view of Bornzin (US Patent 5,891,176) in view of Carlson (US Patent 6,026,324).

16. Regarding Claim 4, see rejection of similarly worded Claim 2 above. As to the activity level measurement means, Kieval discloses an activity sensor 316 optionally coupled to the IPG housing (see col. 10, line 36), thereby coupled to the patient, said activity-level measurement means is derived from a piezoelectric crystal transducer (see col. 10, line 38). Kieval and Bornzin do not disclose that the output signal of said activity-level measurement means is time-synchronized to the hemodynamic monitor means. Carlson discloses that the activity-level output and the hemodynamic monitor output signals in a time-synchronized fashion (see col. 7, lines 10-12). The examiner considers that the activity level measurement means accelerometer 50) must output a signal at the same time the hemodynamic monitor (accelerometer 16) outputs a signal to the microprocessor if the level of physical activity is to be a portion of the hemodynamic signal. It would be obvious to one of ordinary skill in the art at the time of the invention to synchronize the output of the activity level measurement means to the hemodynamic monitor means so the activity level can be easily correlated to the hemodynamic status of the heart and an appropriate AV delay can be determined (see col. 7, lines 10-34).

17. Regarding Claim 9, Kieval and Bornzin do not disclose a bi-ventricular device. The applicant does not disclose any criticality to using a bi-ventricular device over any other type of stimulation/monitoring device. Furthermore, bi-ventricular devices are well

known and common in the cardiac therapy art. Not only that, an AV device would work equally as well as a bi-ventricular device. Nevertheless, Carlson teaches that the method of optimizing a pacing regime could apply to a variety of different devices, including a bi-ventricular device (see V-V pacing; col. 2, lines 13-16). It would have been an obvious design choice to one of ordinary skill in the art at the time of the invention to use a bi-ventricular device as long as a physiological parameter could be measured along with the level of physical activity in order to provide an appropriate therapy.

18. Regarding Claim 10, Kieval, Bornzin, and Carlson all disclose a dual-chamber pacing mode (see Kieval, Figure 4 and col. 7, lines 54-55; see Bornzin, col. 4, lines 48-50; see Carlson, col. 3, lines 18-19).

19. Regarding Claims 11 and 12, Kieval discloses that the hemodynamic data is collected for a preselected period of time (see col. 4, lines 10-13), the preselected period of time being between a few minutes and several days (see col. 12, lines 46-49). The examiner considers that since the initial step of the optimization method includes collecting hemodynamic data (see RVP signals, col. 3, lines 42-44) and the optimization method is performed at pre-determined times of the day for a number of minutes, the collection of hemodynamic data also occurs at pre-determined times of the day for a few minutes.

20. Regarding Claim 13, Kieval discloses that the cardiac stimulation sequence comprises data based at least in part on the lowest estimated pulmonary artery diastolic pressure measured during collection of the hemodynamic data (see col. 3, lines 53-57).

Conclusion

21. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

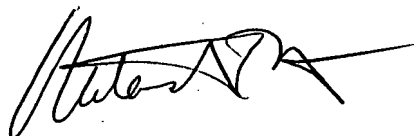
22. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natasha N. Patel whose telephone number is 571-272-5818. The examiner can normally be reached on M-F 8:30-5:00.

24. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3766

25. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Natasha N Patel
Patent Examiner
Art Unit 3766

/Kennedy J. Schaetzle/
Primary Examiner, AU 3766
July 18, 2007